

AD _____

Award Number: DAMD17-01-C-0037

TITLE: Remote Access to Medical Specialists (RAMS) - Remote
Patient Care Monitoring Test Bed

PRINCIPAL INVESTIGATOR: Peter J. Martin, Ph.D.

CONTRACTING ORGANIZATION: Trex Enterprises Corporation
Kihei, Hawaii 96753

REPORT DATE: December 2002

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20030214 160

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE December 2002	3. REPORT TYPE AND DATES COVERED Annual (2 Apr 01 - 31 Dec 02)	
4. TITLE AND SUBTITLE Remote Access to Medical Specialists (RAMS) - Remote Patient Care Monitoring Test Bed			5. FUNDING NUMBERS DAMD17-01-C-0037	
6. AUTHOR(S) : Peter J. Martin, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Trex Enterprises Corporation Kihei, Hawaii 96753 Email: pmartin@trexhawaii.com			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words) The purpose of this program is to demonstrate the applicability of advanced digital medicine techniques to military medicine. It consists of two parts: Critical Care and Chronic Care. The Critical Care portion of this program will enable a doctor at Tripler Army Medical Center (TAMC) to view patients and data from patients in the ICU at USNH Guam. This portion of the program has been subcontracted to VISICU, a company which has installed somewhat similar systems in the past. Delays in the subcontracting process resulted in a request for a no-cost extension of the contract, which was approved. Subsequent delays in installing the required communications circuit between TAMC and Guam have triggered other delays, which have prompted another request for a no-cost extension. The Chronic Care portion will enable a physician to monitor blood glucose and blood pressure taken by patients in their homes from the physician's office. The hardware and software components for the Chronic Care portion are largely complete. The components work in a test setting, but due to difficulties obtaining approvals from IRB and other relevant groups, the hardware and software have not been and will not be tested in a doctor/patient setting during this program.				
14. SUBJECT TERMS: remote access patient care			15. NUMBER OF PAGES 12	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

Table of Contents

Cover	1
SF 298	2
Table of Contents.....	3
Introduction.....	4
Body	5
Key Research Accomplishments.....	8
Reportable Outcomes.....	9
Conclusions	10
References	11
Appendices	12

Introduction

The purpose of the Remote Access to Medical Specialists (RAMS) – Remote Patient Care Monitoring Test Bed program is to demonstrate the applicability of advanced digital medicine techniques to military medicine; from urgent, combat casualty care to peacetime military readiness and dependent care. The RAMS program will focus on the acquisition, transmission, and remote monitoring of real-time patient data on Intensive Care Unit (ICU) patients, and chronically ill patients, either at home or at a remote care site.

Body

This section describes the research accomplishments associated with each task outlined in the approved Statement of Work.

The RAMS program is divided into two major parts: Intensive Care Unit (ICU) Monitor, also referred to as Critical Care Monitor, and Home Care Monitor (HCM), also referred to as Chronic Care Monitor. Some sections below refer to a single document which covers both of these parts; others cover each of these parts separately. Some of the terminology and concepts described in this section assume familiarity with the System Requirements Document, the System Design Document, or the System Test Plan Document, all of which have been submitted as deliverables for this program.

The task titles and numbers in the list below refer to the corresponding tasks as listed in the Statement of Work. For a description of what was planned for each of these tasks, please consult the Statement of Work itself.

1.0 Systems Engineering

1.1 System Requirements

The System Requirements Document has been submitted and approved.

1.2 System Design

The System Design Document has been submitted and approved.

1.3 System Testing Planning

The System Test Plan Document was submitted, and conditionally approved pending changes. Those changes were made, the document was resubmitted. The document is currently pending final approval.

1.4 Human Use Protocol

The ICU Monitor is being installed by VISICU, a subcontractor which developed the system. Trex and VISICU will only be performing technical tests using simulated data. Any human use will be done by doctors and other appropriate medical personnel at Tripler Army Medical Center (TAMC) and United States Naval Hospital (USNH) Guam, after installation is complete. Since this is an FDA approved system, no Human Use Protocol document or approval is required.

An initial Human Use Protocol document for the Home Care Monitor was composed by Trex. This document was delivered to Dr. Vincent, head of Medicine at TAMC, in January 2002. Dr. Vincent and others at TAMC attempted to modify this document in a way that would enable it to be approved by the TAMC Institutional Review Board (IRB), the MRMC IRB, and other appropriate approval boards, but he was unsuccessful in reconciling the differing requirements of the boards. In May 2002 Trex and RAMS project management at TAMC came to the conclusion that there was no longer enough time left in the project to pursue human testing for this part of the program.

2.0 Testbed System Development

2.1 Design

Designs of testbed systems for both parts of this program are shown in the System

Design Document, which has been submitted and approved.

2.2 Fabrication

The ICU Monitor system has been assembled, configured, and tested by VISICU at VISICU headquarters in Baltimore, MD.

Prototype Home Care Monitor system hardware was designed and assembled by BioSTAR, a subcontractor. Thirty (30) units of this hardware have been procured and assembled, and are currently available for use. Firmware controlling this hardware was written by both Trex and BioSTAR. Three of the four major sections of this firmware are complete, and the fourth section is close to completion. Software for the server which stores measurement data and displays that data to physicians and other medical personnel was written by Trex, with input and approval from Dr. Vincent, Head of Medicine at TAMC. This software is complete.

2.3 Integration and Testing

As mentioned above, components of the ICU Monitor system have been assembled, configured, and tested by VISICU at VISICU headquarters.

Home Care Monitor system hardware and software components have been integrated and tested in a laboratory test environment, but due to difficulties getting approval for the Human Use Protocol, final integration and testing has not been completed.

3.0 Clinical System Development

3.1 Install Equipment

The communications line required for the ICU Monitor system has been installed between TAMC and USNH Guam. Installation of the other system components is planned for March and April 2003.

Components of the Home Care Monitor system have not been installed in a clinical environment, due to difficulties getting approval for the Human Use Protocol.

3.2 Data Collection

The ICU Monitor system has not been installed, so no data has been collected.

The Home Care Monitor system has not been deployed, so no data has been collected.

3.3 Data Reduction and Analysis

No work has been done on Data Reduction and Analysis, because no data has been collected for either of the two major parts of this program.

4.0 Management

4.1 Program Management

Overall approaches for each of the two major parts of this program were discussed, evaluated, and chosen. Subcontractors were solicited, evaluated, and selected for each of these parts. Subcontracts were negotiated with VISICU for the ICU Monitor System and with BioSTAR for the Home Care Monitor system development. Trex has monitored and directed the performance of these subcontractors, with frequent phone calls, email, and teleconferences, and occasional face-to-face meetings. During the Period of Performance of this program, Trex has held many teleconferences with the technical and clinical participants of this program, to communicate project progress and to coordinate planning.

4.2 Travel

Trex personnel have traveled as necessary for the performance of other tasks listed in this document.

4.3 Report Preparation

The System Requirements Document has been submitted and approved.

The System Design Document has been submitted and approved.

The System Test Plan Document has been submitted and is awaiting approval.

Quarterly Progress Review (QPR) meetings have been held, and hard copies of the PowerPoint presentation slides for each QPR have been delivered for each meeting.

This Annual Progress Report has been submitted and is awaiting approval.

All other reports for this program cover work which is not yet complete, so they are pending completion of the appropriate work.

4.4 Meetings

During much of the Period of Performance of this program, weekly teleconferences have been held to communicate project progress and to coordinate planning. Some of these meetings have been periodically postponed or canceled when all parties involved agreed that the particular meetings were not necessary, or when appropriate personnel were not available at the scheduled meeting time. A Quarterly Progress Review has been held once each quarter, where Trex, occasionally in conjunction with one of its subcontractors, presents a report on progress to date on this program.

Key Research Accomplishments

- No research accomplishments can be reported for the ICU Monitor System, as that system has not yet been installed.
- No research accomplishments can be reported for the HCM System, as that system has not been installed.

Reportable Outcomes

This section is to include manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue, or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award.

With the exception of internal presentations to TAMC and USNH Guam personnel, none of these has been produced during this program.

Conclusions

The process of soliciting, evaluating, and choosing a subcontractor to provide the Intensive Care Unit monitor part of this program has shown that multiple commercially available solutions now exist which can provide partial solutions to the Remote Patient Monitoring problem. While these systems have previously been used to provide monitoring from a distance of tens of miles, when complete, this part of this program will show that appropriate modifications to and combinations of such systems can provide effective monitoring from several thousand miles (TAMC and USNH Guam are approximately 4000 miles from each other).

The development of the Home Care Monitor system has shown that such a system can be built fairly inexpensively, using tried-and-true hardware components and developing a few new software components. The larger problem proved to be obtaining information from the various boards and other groups from which approval was needed to deploy this system.

References

No references are included in this report.

Appendices

No appendices are included in this report.